Appointment

From: Herrick, Jacquelyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40da8860b1dd43d9b006ac1e0e9e04ce-Marchese, J]
Sent: 4/1/2021 11:47:34 AM
To: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Leifer, Kerry [Leifer.Kerry@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]
CC: Koch, Erin [Koch.Erin@epa.gov]; Pittman, Forrest [Pittman.Forrest@epa.gov]

Subject: PRN 11-3 Questions - Clarke Container Submissions
Location: Microsoft Teams Meeting

Start: 4/1/2021 3:30:00 PM
End: 4/1/2021 4:00:00 PM
Show Time As: Busy

Required Attendees: Leifer, Kerry; Sadowsky, Don
Optional Attendees: Koch, Erin; Pittman, Forrest

Can we chat real quick about the registrant's concerns over our request for a laboratory's methodology to be formatted per 11-3?

The email chain I have with the registrant is quite long, so I just copied the most recent email below, and bolded the relevant part for our discussion. I can offer more context to the discussion in the call.

Many thanks,
Jackie

Jackie,

Clarke has already granted letter of access to MGK (see attached). Can you clarify whether this was submitted by MGK?

I continue to be confused over this and suspect it has been unnecessarily jumbled into a bureaucratic mess. MGK and other basics will be relying exclusively on the information Clarke has provided for Clarke's newly sourced container. Clarke's supplemental registrations are of minor consideration to their business, and we appreciate greatly their cooperation to expedite submissions on our behalf. However, given your request earlier this week for a resubmission from Eurofins, what direction can Clarke provide them now?

It is still not clear whether a Eurofins submission of a *reformatted appendix to Clarke's report* will require a new MRID and submitter assignment or whether it will be a supplement to the existing MRID. Since RD is requiring MGK (and others) to cite Clarke's submitted report, inclusive of the appendix, will they need a letter of access from Eurofins as well? This seems unnecessarily complex and bears a low probability of success in a short timeframe. What of the existing submissions and data matrixes? Do these also require resubmission? This all seems unnecessarily burdensome given the nature of the review!

The container evaluation data does not in any way describe any testing on any pesticide product and was submitted *voluntarily* in response to an *informal* inquiry from RD. It is not specific, even, to the container that is being evaluated! It simply reveals a proprietary method which complies with all EPA Office of Water and DoD guidance for the testing of PFAS in water and other media. Will RD now be requiring the same container testing and submission requirements of every registrant proposing a new container, or a new registration in any container whether or not new, or is this a standard applied only to Clarke?

I do understand these are unprecedented questions for industry and OPP to be grappling with, but while RD delays a review over administrative issues Clarke continues to be unable to meet customer demand for product packaged in small containers and refillable plastic drums, *and* alternative products remain commercially available in traditionally fluorinated packaging.

I submit again my offer to resubmit the container evaluation with the same MRID and absent the voluntarily included SOP in the appendix.

Karen

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